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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,487	02/14/2001	Tito Andrew Serafini	10239-010	7095

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NEW YORK, NY 100362711

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/783,487	Applicant(s) SERAFINI, TITO ANDREW	
	Examiner Joseph Weitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-158 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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Election/Restriction

This is an original application, filed February 14, 2001.

Applicant's preliminary amendment filed August 20, 2001, paper number 7, has been received and entered. The specification has been amended. Claims 124, 134, 146 and 153 have been amended. Claims 1-158 are pending and currently under examination.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27, drawn to a collection of lines of transgenic animals containing a single transgene, classified in class 800, subclass 8.
- II. Claims 28-31, drawn to a collection of lines of transgenic containing two or more transgenes, classified in class 800, subclass 8.
- III. Claims 32-60, drawn to a method of making a collection of lines of transgenic animals containing a single transgene, classified in class 800, subclass 21.
- IV. Claims 61-64, drawn to a method of making a collection of lines of transgenic containing two or more transgenes, classified in class 800, subclass 21.
- V. Claims 65-91, drawn to a collection of vectors containing a transgene, classified in class 536, subclass 23.1.
- VI. Claims 92-94, drawn to a collection of vectors containing a transgene and a second sequence, classified in class 536, subclass 23.1.

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VII. Claims 95-123, drawn to a method of making a collection of vectors, classified in class 435, subclass 91.4.

8-364. Claims 124, drawn to a transgenic animal comprising a single transgene recited in claim 124 (356 possible genes recited), classified in class 800, subclass 8.

365-701. Claims 125-134, drawn to a transgenic animal containing a two or more transgenes wherein one gene is selected from the group recited in claim 124, classified in class 800, subclass 8.

702. Claims 135-145, drawn to a method of isolating cells from two or more transgenic animals, classified in class 435, subclass 1.1.

703. Claim 146, drawn to a pure population of cells, classified in class 435, subclass 325.

704. Claims 147-152, drawn to a method of screening compounds for potential effects on one or more cell types, classified in class 435, subclass 455.

705. Claims 153-158, drawn to a method of screening compounds for potential effects on transgenic animal, classified in class 800, subclass 21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III, and II and IV are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

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instant case transgenic animals can be generated by a variety of methods known in the art and do not require the methods set forth in groups III and IV. Further, the process as generally claimed can be used to generate chimeric animals, rather than transgenic animals.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise two different types of transgenic animals capable of separate use. In each case the animals contain a different number of transgenes and thus, their genome are physically different and may demonstrate phenotypic differences.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different vectors comprise number and types of transgenes, and thus, are physically different. Further, each type of vector has a separate and distinct use.

Inventions VII and V, VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case vectors can be made by a variety of different methods known in the art.

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Inventions 8-364 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a transgenic animals capable of separate use. In each case the animals contain a different transgenes and thus, their genome are physically different and the animal may demonstrate phenotypic differences one from the other.

Inventions 365-701 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a transgenic animals capable of separate use. In each case the animals contain a different transgenes and thus, their genome are physically different and the animal may demonstrate phenotypic differences one from the other.

Inventions 8-364 and 365-701 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a transgenic animals capable of separate use. In each case the animals contain a different transgenes and thus, their genome are physically different and the animal may demonstrate phenotypic differences one from the other.

Inventions 702 and 703 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

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claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one can isolate cells from a variety of different sources. Additionally, the cells containing a transgene can be generated by inserting the gene of interest into cells isolated from normal animals.

Inventions 703 and 704 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be done with cells containing a variety of different transgenes or with normal cells. Further, the product could possibly be used to study other physiological effects.

Inventions I and 705 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be done with animals containing a variety of different transgenes or with normal animals. Further, the product could possibly be used to study other physiological effects outside a general screening method.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

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Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Voitach

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AU1632